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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,652	01/22/2005	Oleg Iliich Epshteni		8482
<div>I Zborovsky 6 Schoolhouse Way Dix Hills, NY 11746</div>				
7590		07/12/2007	<div>EXAMINER WEN, SHARON X</div>	
			<div>ART UNIT 1644</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 07/12/2007</div>	<div>DELIVERY MODE PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/522,652

Applicant(s)

EPSHTENI ET AL.

Examiner

Sharon Wen

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. The art unit location of the examiner of this application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Sharon Wen, Group Art Unit 1644, Technology Center 1600.

#### ***Election/Restrictions***

2. Applicant's election of Group I and species interferon alpha, in the reply filed on 04/20/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-5 are pending.

Claims 4-5 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claims 1-3 are currently under examination.

#### ***Priority***

3. The effective priority date for claims 1-3 is deemed the filing date of PCT/RU02/00369, i.e. 08/02/2002.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite the terms "activated", "low or ultra-low" and "external" which are relative terms that render the claims indefinite. The terms "low or ultra-low" and "external" are not defined by the claim, the specification does not provide the standard for ascertaining the

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requisite degrees, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add New Matter. See MPEP 714.02 and 2163.06.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3 rejected under 35 U.S.C. 102(e) as being anticipated by Chuntharapai et al. (U.S. Patent 7,087,726 B2, see entire document).

Under the broadest reasonable interpretation, the recitation of a “medicament” or a “medicament based on antibodies” reads on a composition comprising an anti-IFN alpha antibody wherein the composition is in low or ultra-low doses. Given the “comprising” language, Chuntharapai et al. anticipates the instant claims because the reference teach a medicament comprising the anti-IFN alpha antibody wherein the medicament is administered in low or ultra low doses (see column 6, lines 54-57, column 45, lines 60-68; column 47, lines 47-57).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chuntharapai et al. (U.S. Patent 7,087,726 B2) in view of Cavazza (U.S. Patent 5,683,712).

Chuntharapai et al. teach a monoclonal antibody to interferon alpha (see entire document, in particular, see Summary of the Invention and claims 1-34). In addition, Chuntharapai et al. further teach a medicament based on the anti-IFN-alpha antibody (see column 6, lines 54-57).

Chuntharapai et al. does not teach the antibody in low or ultra-low doses in accordance with homeopathic technology.

However, Cavazza teaches that preparing therapeutic drugs in accordance with homeopathic technology is well known in the art (see entire document, in particular, column 1, lines 11-20). In addition, Cavazza teaches how to prepare the active ingredients by a process called potentization consisting in a succession of dilution which result in an extremely low or ultra low dose of the active ingredient (see column 1, lines 21-36).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to produce the medicament comprising the monoclonal antibody to IFN-alpha as taught by Chuntharapai et al. in accordance with homeopathic technology as demonstrated by Cavazza.

One of ordinary skill would have been motivated to produced a medicament comprising an antibody to IFN-alpha in accordance with homeopathic technology because of the teaching by Chuntharapai et al. on using the anti-IFN-alpha antibody for treating autoimmune diseases (see column 6, lines 63-68) and the teaching by Cavazza that in order to induce the desired therapeutic effect, low doses of homeopathic remedy should be given (column 1, lines 15-20).

Therefore, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

10. No claim is allowed.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Wen whose telephone number is (571) 270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Wen, Ph.D.

Patent Examiner

June 27, 2007

  
PHILLIP GAMBEL, PH.D. JD  
PRIMARY EXAMINER  
TZ 1600  
7/6/07